Health Care Costs and Resource Use Associated with Sequelae and Comorbidities in Patients with Chronic HCV

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BACKGROUND

- Patients with chronic HCV incur substantial health care utilization and costs due to sequelae from the virus as well as from conditions other than HCV.
- Understanding costs and resource use associated with sequelae and comorbidities may help to inform treatment and health care coverage decisions.
- Healthcare resource utilization and costs for the U.S. are often estimated using retrospective claims databases. Since the available databases represent small proportions of the U.S. population, the use of several databases are helpful to get generalizable estimates. Results from this study are based on data from over 97,000 patients with chronic HCV.
- The purpose of this study was to determine the financial impact of sequelae and comorbidities in patients with chronic HCV.

METHODS

Study Design

- A retrospective cohort analysis was conducted using 2 large commercially paid claims databases (Claims DB1 and Claims DB2) with claims from 2006-2013.

Sample Selection

- Adults with a diagnosis of chronic HCV (ICD-9 070.44, 070.54) continuously enrolled for 2 years prior to the index date were included. The index date was set as the last ICD-9 code for an HCV patient with 1 year of continuous enrollment post-index date.

Baseline and Outcomes Variables

Patient Characteristics

- Demographic characteristics such as age and gender were captured.
- Patients were stratified into subgroups based on comorbidities of interest: cirrhosis (decompensated or compensated), liver transplant, hepatocellular carcinoma (HCC), prior HCV treatment status, HIV co-infection, diabetes, cardiovascular disease (CVD), psychiatric disorders, and renal disease. The proportion of patients with each comorbidity was captured.
- For HCV-related sequelae, patients were placed in mutually exclusive groups. If a patient had more than one of the sequelae, preference was as follows: transplant > decompensated cirrhosis > compensated cirrhosis.

Resource Utilization and Costs

- Resource utilization and costs were captured from the 1 year time period following the first claim for the comorbidity of interest in the baseline period.
- The percentage of patients with at least one hospitalization or emergency room (ER) visit was calculated for each database. The average number of hospitalizations and ER visits were also captured, and the average length of stay (LOS) was also calculated for hospitalizations.
- Costs were calculated on a mean per patient per year (PPPY) basis. Overall costs (regardless of comorbidity status), costs by comorbidity, costs for patients with at least 1 comorbidity, costs for patients without any of the selected comorbidities, and costs by comorbidity status were captured.

Statistical Analyses

- Basic descriptive statistics were calculated for baseline demographics and unadjusted costs. Unadjusted mean PPPY costs were calculated for overall costs and by sequelae/comorbidity stratification.
- Comorbidity costs were adjusted for age and gender using a 2 part generalized linear model (GLM) with a gamma distribution and log-link function. Adjusted mean PPPY costs were calculated for patients with at least 1 comorbidity, and patients with no comorbidities of interest.
- Costs were converted to 2013 dollars using the urban component of the Consumer Price Index[1], and all analyses were conducted using SAS version 9.2.

RESULTS

- Results from the two databases representing more than 212,000,000 covered lives yielded information for 97,935 patients with chronic HCV (Figure 1).

Figure 1. Sample Selection

Selection Criteria	Claims DB1	Claims DB2
Diagnosis of Chronic HCV	n=355,691	n=280,227
≥18 years of age on index date	n=356,354	n=278,074
2 years continuous enrollment pre-index	n=150,219	n=137,049
1 year continuous enrollment post-index	n=46,384	n=51,551

RESULTS (cont)

Patient Characteristics and Comorbidities

- Baseline demographics were similar between the databases. More than half of patients were male, and the average age was 52-53 years (Table 1).
- With regards to HCV-specific sequelae, slightly more than 5% of patients had compensated cirrhosis, slightly less than 5% had decompensated cirrhosis, and transplant percentages ranged from 0.83% to 2%, respectively (Table 2).
- CVD was the most common comorbidity among patients, with nearly half (48%) of patients in each database with a diagnosis for CVD. Mental disease was also common in both databases, affecting more than 20% of patients (Table 2).

Table 1. Patient Characteristics

	Claims DB1 (n = 46,384)	Claims DB2 (n = 51,551)
Gender, n (%)		
Males	26,507 (57.1)	30,074 (58.3)
Females	19,877 (42.9)	21,476 (41.7)
Age, mean (SD)	53.5 (11.2)	52.3 (11.0)
Age group, n (%)		
18-34	3,083 (6.6)	3,999 (7.7)
35-44	4,639 (10)	5,565 (10.8)
45-54	14,860 (32)	18,021 (35)
55-64	19,687 (42.5)	20,016 (39)
≥65	4,115 (8.9)	3,860 (7.5)

Table 2. Comorbidities of Interest Among Patients with Chronic HCV

	Claims DB1 (n = 46,384)	Claims DB2 (n = 51,551)
Transplant, n (%)*	928 (2.0)	430 (0.8)
Cirrhosis, n (%)*		
Decompensated	2,048 (4.4)	2,529 (4.9)
Compensated	2,355 (5.1)	2,771 (5.4)
HCC, n (%)	648 (1.4)	707 (1.4)
Treatment experienced, n (%)	2,770 (6.0)	3,272 (6.4)
HIV, n (%)	1,050 (2.3)	1,148 (2.2)
Diabetes, n (%)	7,653 (16.5)	7,967 (15.5)
CVD, n (%)	22,025 (47.5)	24,750 (48)
Mental disease, n (%)	9,451 (20.4)	11,986 (23.3)
Renal disease, n (%)	4,101 (8.8)	4,519 (8.8)

*Groups were mutually exclusive (Transplant > Decompensated cirrhosis > Compensated cirrhosis
Key: CVD= cardiovascular disease, HCC= hepatocellular carcinoma, HIV= human immunodeficiency virus

Resource Utilization

Patients with at least 1 Hospitalization

- As inpatient hospitalizations were the primary cost driver, detailed information pertaining to hospitalization resource utilization is presented in Table 3.
- In both databases the overall percentage of patients with at least 1 hospitalization was approximately 18% regardless of comorbidity status. For patients without a comorbidity, the percentage of patients with at least 1 hospitalization was approximately 10%.
- Generally speaking, HCV sequelae accounted for higher percentages of patients with a hospitalization. In DB1, patients with HCC had the highest percentage of patients with a hospitalization (53.7%), while patients with a liver transplant had the highest percentage of patients with a hospitalization in DB2 (61.6%). The percentage of patients with DB1 at 54.6%.
- Renal disease had the highest percentages of patients with a hospitalization when other comorbidities were examined.

Hospital LOS

- Average LOS regardless of comorbidity status was 7.7 days for DB1 and 10.6 days for DB2. Patients without a comorbidity had a LOS of 4.9 days or 5.9 days, depending on the database evaluated.
- LOS was longest for patients receiving a liver transplant, a trend that held across both databases (14.5 days for DB1 and 18.7 days for DB2).
- When other comorbidities were evaluated, patients with renal disease had the longest LOS in both databases, followed by patients with mental disease.

Table 3. Hospitalizations Among Patients with Chronic HCV

	Claims DB1			Claims DB2		
	Pts with ≥1 Hospitalization (%)	Avg No. Hospitalizations (SD)	Avg LOS in Days (SD)	Pts with ≥1 Hospitalization (%)	Avg No. Hospitalizations (SD)	Avg LOS in Days (SD)
Overall	8,331 (18.0)	1.5 (1.2)	7.7 (14.4)	9,573 (18.6)	1.7 (1.8)	10.6 (24.5)
HCV Sequelae						
Transplant	412 (44.4)	2.0 (1.8)	14.5 (23.0)	265 (61.6)	2.2 (1.8)	18.7 (33.4)
Decompensated Cirrhosis	1,047 (51.1)	2.0 (1.6)	12.8 (18.4)	1,357 (53.7)	2.5 (2.2)	16.9 (25.2)
Compensated Cirrhosis	521 (22.1)	1.6 (1.1)	7.0 (8.9)	646 (23.3)	1.8 (1.4)	9.9 (18.0)
HCC	348 (53.7)	2.0 (1.6)	12.0 (18.0)	386 (54.6)	2.5 (2.2)	14.7 (19.6)
Treatment Experienced	308 (11.1)	1.5 (1.0)	6.5 (9.8)	336 (10.3)	1.5 (1.0)	7.9 (13.5)
Other Comorbidities						
HIV	200 (19.1)	1.8 (1.4)	9.9 (3.0)	254 (22.1)	2.1 (1.8)	11.6 (15.4)
Diabetes	2,073 (27.1)	1.8(1.6)	9.4 (13.7)	2,219 (27.9)	2.0 (1.8)	13.2 (25.7)
CVD	5,972 (27.1)	1.7 (1.4)	8.9 (15.9)	6,628 (26.8)	1.9 (1.8)	12.1 (24.7)
Mental Disease	2,652 (28.1)	1.9 (1.7)	10.5 (20.0)	3,422 (28.6)	2.1 (1.9)	13.7 (24.4)
Renal Disease	1,800 (43.4)	2.1 (1.8)	13.8 (23.6)	1,939 (42.9)	2.5 (2.4)	20.6 (37.2)
HCV but No Comorbidities	1.577 (10.0)	1.2 (0.7)	4.9 (8.2)	1,853 (10.6)	1.3 (1.2)	5.9 (12.4)

*Groups were mutually exclusive (Transplant > Decompensated cirrhosis > Compensated cirrhosis
Key: Avg= average, CVD= cardiovascular disease, HCC= hepatocellular carcinoma, HIV= human immunodeficiency virus, LOS= length of stay, Pts= patients, SD= standard deviation

Costs

- Overall unadjusted PPPY costs (regardless of comorbidity status) were approximately $13,200 per year for all chronic HCV patients.
- When HCV sequelae were evaluated, transplant patients incurred the highest PPPY costs. Transplant costs were more than $30,000 higher for patients in Claims DB2, which illustrates the value in evaluating costs across databases (Figure 2).
- HCC costs were similar to transplant costs in Claims DB1, while compensated cirrhosis costs were the lowest in both databases (Figure 3).

Figure 2. Unadjusted PPPY Costs for HCV Sequelae

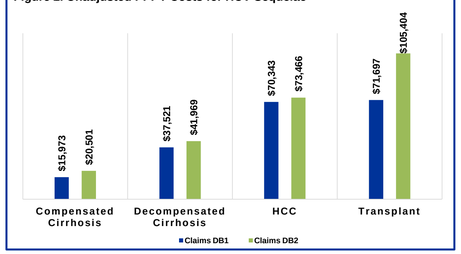
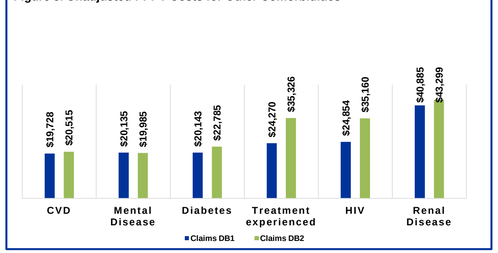


Figure 3. Unadjusted PPPY Costs for Other Comorbidities

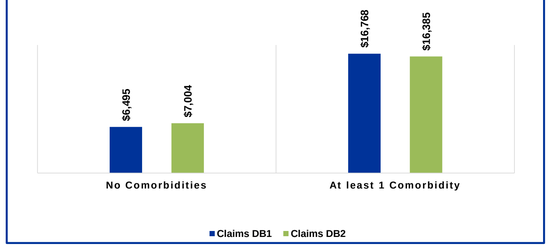


RESULTS (cont)

Costs (cont)

- Interestingly, a high percentage of patients with decompensated cirrhosis had a hospitalization and/or ER visit, but these patients did not incur the highest costs ($15,973 and $20,501, respectively) (Table 3 and Figure 2).
- Though almost half of patients had a CVD diagnosis, this group accounted for the lowest unadjusted PPPY costs (Figure 3).
- Renal disease accounted for the highest costs among other comorbidities evaluated, but were still lower than costs in patients with HCC or transplant (Figures 2 and 3).
- When costs were adjusted using a GLM approach, patients with at least 1 comorbidity incurred more than twice the amount of costs incurred by patients without a comorbidity, illustrating the financial impact that comorbidities have on patients with HCV (Figure 4).

Figure 4. Adjusted PPPY Overall Costs by Comorbidity Status



DISCUSSION

- Results from this study represent real-world data from two large claims databases. Information gleaned from this analysis can help to further understand resource utilization in this population. This data can be used by a myriad of health care professionals in making treatment and care decisions for patients with chronic HCV.
- It should be noted that the patient characteristics from this study align with the CDC recommendations for birth cohort testing for HCV for persons born from 1945-1965.[2]
- Prevalence estimates from this study were lower than those reported nationally (0.046% vs 1.1%[3]). This discrepancy may be largely attributable to the continuous 3-year eligibility requirements for inclusion in the study, and/or the fact that it is limited to a predominately commercial population with chronic HCV.
- As with all database studies, results are subject to the accuracy and coding of the claims. HCV is likely to be underestimated in the general population, and sequelae such as cirrhosis and liver transplants are likely to be underestimated in claims data. Additionally, due to inability to capture clinical data in claims analyses, information regarding the severity of sequelae/comorbidities is not possible to assess.
- Data from this study precede the advent of newer therapies for HCV. Costs associated with these therapies are not reflected in the results of this study, and results should be interpreted with this in mind.

CONCLUSIONS

- Health care resource utilization and associated costs for patients with chronic HCV are substantial and vary considerably by associated sequelae/comorbidities.
- HCV sequelae and other comorbidities contribute heavily to the economic burden associated with HCV. Understanding and quantifying the contributions of these conditions on the health care system may help inform decision makers.
- Further research evaluating the impact of newer therapies for HCV is warranted to better understand the short-term and long-term implications of therapy on resource utilization and costs in a chronic HCV patient population.

REFERENCES

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DISCLOSURES

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